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answering that initial question that I proposed? Did they get their illness from exposure to a Grace product?

Q I'm showing you 2283. Could you explain exactly why the issue is framed in the way or question is framed in the way reflected on 2283?

A Yes, and the question really is exactly this question, what does science say about the significance of doses resulting from exposure to Grace products.

Q In order to answer that question, I see that the next step is reflected in 2269. Just to compare the doses to these benchmarks, could you describe in your own terms what is involved in that exercise?

A Yes, as I spoke of earlier, we spoke of the Koch principles. We spoke of the world of epidemiology and dose response, and I know that this Court has heard from Dr. Moolgavkar who works in this particular field, and the concept of having now these cumulative exposures and asking this essential question really is what does it mean in terms of disease causation or these high levels, low levels, how can we compare them to some benchmarks that might give us guidance as to their significance.

Q What benchmarks did you use?

A I used benchmarks from Dr. Moolgavkar's analysis, and I think I emphasized in my deposition that I have the utmost confidence in Dr. Moolgavkar, but there's a long history here.

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PP Obj: R; F; UP; H; ET; LA

There's a longer history than just his opinions, because this work has been evolving over many, many years, and his work is the essential work that brings all of this literature together, but we find a great deal of support in the literature for his work.

Q Have you offered an independent opinion with respect to the epidemiology, or are you relying upon Dr. Moolgavkar's work?

A I'm relying on Dr. Moolgavkar's work.

Q I'm showing you 2262. Is this --

MR. BERNICK: I believe, Your Honor, it may actually already be in evidence under a different number.

Q But are these the benchmarks -- from what Dr. Moolgavkar, but are these the benchmarks that you used in the course of your analysis?

A Yes, they are.

Q Okay. Now, Dr. Moolgavkar talked about the fact that there were not reliable data -- observational data that was gathered below 15 -- a burden of 15 fibers per mil per year. Are you familiar with the 15 fiber per mil -- fiber per mil per year concept?

A Yes, I am.

Q Okay, and he then further observed that once you get below 15, you're in, therefore, a range of the unobserved, and then below 2.8, which came from the auto workers study or the auto

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mechanics study, you were in a range of risk, in a sense, affirmatively not being seen. Now, I don't want to ask you about the details of those different numbers. I simply want to ask you are you familiar with those basic concepts? That is a range of observed data -- reliably-observed data, a range where there isn't reliable observational data, and then an area where there is reliable observational data, but it doesn't show a risk.

A Yes, I am, and we have spoken of this concept since 1976.

Q I want to show --

A The range of observation --

Q Wait. Let me interrupt you for just a second --

A Yes.

Q -- and just put on the board 2284, which I believe already has been used by Dr. Moolgavkar, but I'm -- my focus with you is to simply have you, as you were beginning to say, provide the historical regulatory perspective. That's what I want you to comment on, is the regulatory side of what is illustrated in that chart.

A Yes, I spoke earlier on the earlier slide of the divergence between evidence of causality and evidence that is a preemptive public health policy-based approach. And here the first one of these curves was drawn when I was at EPA in 1976. Conceptually, we see with agents an observed range from human studies, sometimes only animal studies, but the important thing

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is as we leave that range of observation, we regard that range as science based.

As we go downward, EPA to this day -- and we created this curve in 1976 as a means of establishing a plausible upper bound on the risk, meaning the real risk could be less even approaching zero, and we put that label on every document that we wrote at EPA when I was there. And I think the other important thing is I've observed the use of this generic approach by the National Academy of Sciences and the Institute of Medicine. I was familiar with and commented on some of their work, and an example of that work is the Gulf War veterans study where they actually made distinctions about establishing causality from exposure for those individuals and chose to use only the observed range for that work.

Q Thank you. And that gets back to the difference between science --

A That's right.

Q -- and the regulatory guidance or rule?

A That's right, and the inference judgments that I used to fill gaps, so that rule making can go forward.

Q Thank you. I want to now turn to how it is that you used -- if we could go back to 2262, you said that you used Dr. Moolgavkar's benchmarks. I want to talk about how it is that you applied or used those benchmarks by reference to the cumulative doses that you determine in part on the basis of Dr.

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Lees' with an S work. And I want to show you Exhibit 2285 and ask you whether this would assist you in explaining to the Court the comparison that you did. The answer to that is yes or no.

A Yes, I think it will assist us.

Q Okay, so now could you explain how -- what it is that is reflected in 2285?

A Yes, the values that we saw earlier and which are displayed here as the dose cumulative exposure values can now be compared to these benchmarks to give us some guidance as to what they mean. We see for the A category an accedence of these conservative screens of the 15. We see for the B category an accedence of no benchmark. For the C category the maximum is a 12, so it's below the 15. It's in the zone of inference. It's above the relative risk, a modeled calculation for Libby Fibers, but it's -- well, let's move on to D. D and E are very small exposures relative to the benchmarks, and they are under all of the benchmarks.

Q Okay. This compare --

A And I should note that the 3.2 number is a mixed fiber number that includes chrysitolite, which is the most potent of the fibers and is not in the Grace product, so I don't take that benchmark to be particularly useful.

Q That's the one that's --

THE COURT: Which one? I'm sorry. Which one. I'm

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sorry?

THE WITNESS: Three point two.

THE COURT: Point two.

THE WITNESS: It's referred to as meso-relative risk to mixed fibers.

THE COURT: Okay.

THE WITNESS: My understanding from speaking with Dr. Moolgavkar is that's taken from --

MR. MULLADY: Objection, Your Honor.

THE WITNESS: -- an EPA --

MR. MULLADY: Objection, Your Honor, the witness is about to tell us about a conversation she had with Dr. Moolgavkar about these fiber concentrations. That's hearsay.

THE COURT: She is, but --

MR. BERNICK: No, it --

THE COURT: -- Dr. Moolgavkar's already made that same statement yesterday on the stand.

MR. BERNICK: Right, but it's -- she's an expert.

THE COURT: He also testified to that same fact on the stand yesterday. The record will substantiate that. He made the same statement on the stand yesterday.

MR. BERNICK: Right.

BY MR. BERNICK:

Q Just to review briefly, we have marked here the 2.8, which he said came from the auto workers study or the risk was not

PP Obj: R; F; UP; H; ET; LA

observed, the relative risk calculation -- relative risk of 2 with respect to mixed fibers, the 3.2, the working lifetime exposure, the OSHA fell 4.5, the relative risk of 2 for -- based on modeling for Libby fibers and meso, 15 which is the lowest observed average exposure for meso, and then ranging way up to asbestosis threshold, chrysotile, relative risk of 2 and the like. Now, does Exhibit 2285 accurately summarize the comparative data that you used in connection with benchmarking the dose -- the cumulative doses with respect to the five categories?

A Yes, it does.

Q I want to turn to ask you and show you 2286. Could you explain, based upon the comparison that you did, what determinations you made with respect to the exposures as determined in accordance with your risk assessment? What assessment did you make with respect to the exposures of people who worked in occupations A, B, C, D, and E? What decision or what determination did you make?

A Well, I found unequivocally that people in Categories B, D, and E are well below all of the benchmarks and need not be considered further. The Categories A and C claimants I have suggested should be further evaluated despite the fact that the C category is below the observed benchmark, and they have passed through -- if we want to call this a screening exercise, those two categories have passed through for further analysis

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but not B, D, and E.

Q I want to take the last step now that we see on the board, 2296, which we see it's called Risk for Claimants. Why is it that risk assessment goes beyond the comparison of calculated doses in benchmarks? Why is it that the risk assessment takes another step?

A I'm not sure I understand the question.

Q Yes. Well, why do we have another step to take here?

A Oh.

Q Why another step?

A Well, I mean the important issue, as I understand it, is what are the merits of these claims going forward, and the information that I have now provided, as I understand it, will go into a claims review analysis for further evaluation. So the results of this analysis now go to the claims reviewers and Dr. Florence.

Q So we're talking about a risk for a population of people.

A That's right.

Q Okay. Now, in order to get into this area could you tell the Court whether or not at your direction the PIQs -- a certain number of PIQs and a certain number of closed claims were reviewed?

A Yes, they were.

Q Okay, and showing you 2289, does this reflect -- 2289 first. Does this reflect the claims that reviewed by people in

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your organization at your direction for purposes of figuring out what categories they belong?

A Yes.

Q Okay, and we have 15 hundred 96 mesothelioma claims, 32 lung cancer claims, 115 laryngeal cancer claims, 152 non-malignant disease claims, and then with respect to the closed claims, 350 mesothelioma claims. Is that right?

A That's correct.

Q Okay. Now was there a procedure -- were there procedures established for purposes of this review?

A Yes, there were very strict procedures established with the team who did the review?

Q Showing you 2288, does this slide -- would this slide assist you in explaining the procedures or the steps that were taken in order to conduct this review?

A Yes, it does. We first needed to and did design a protocol to insure the proper assignment of claimants to the nature of exposure categories that would be consistent with Dr. Lees' definitions of exposure.

Q Okay. Let's -- Dr. Lees' defined categories on the basis of those definitions looked for corresponding industrial hygiene data, and then in order -- and then in doing the claims review to find out what categories people belonged in, tell us why it was important for the same definitions to be used. That is not just the definitions that somebody else might think of

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like a claimant or a worker or anybody. Why was it important to use Dr. Lees' definitions in reviewing the claim files?

A Because we were assigning these claimants to a nature of exposure category, and he had defined that category and collected the data, analyzed the data, and presented the data. So the two had to mesh. They had to be identical, as close as we could get them.

Q Okay. Why don't you continue to go on and talk about the steps that were undertaken thereafter in connection with the review?

A Well, next the review team was identified, obviously choosing people with appropriate experience and credentials. We established training sessions. We established quality control procedures. We had double review. And the actual claims review proceeded along the following lines. Obviously, the claims were inconsistent, and there were times when things were not quite as simple as other times, but we, first of all, accepted the self-identified claimants. If they checked the box that they were asked to check, A, B, C, D, or E, we accepted that. If they checked more than one box, we elevated their exposures to the highest exposure category. So they'd become an A or C instead of if they checked all boxes.

If a claimant did not self-identify, then we bent over backwards to review the attached materials referred to here as best evidence. We wanted to try as hard as we could to

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classify the claimants from that attached material. So we did review the attachments, and we looked for identifying statements of what kind of product they were exposed to, how they were exposed, and over what durations.

Q Okay.

A If, in fact, there was insufficient information and after all of the review we called it insufficient, allocated it to insufficient category, and I've already mentioned always elevating to the highest category if they mentioned several possible exposures.

Q I want to focus on one particular feature, which you've just talked about, and use Slide 2290 to do that.

MR. BERNICK: Could you show 2290, P.J.?

Q There have been questions asked about, well, what if somebody says here's what my job was, and so I -- and I want you to explain how it is that you figured out what category a claimant belonged in where they had actually checked off the box on the form or not checked off the box on the form.

A Well, if they checked off the box on the form, we call that the claimant's identified the nature of exposure. We did not question that. If they checked the box, we accepted it.

Q Or if their lawyer checked the box, and they signed off on it.

A That's right.

Q Okay.

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A Whoever checked the box, it was accepted. We then went to the attached materials where there was no self-identification, and we reviewed the claimant's information that was attached. And I think I've discussed some of the elements of that review. If there were inconsistencies, if there were questions, we had a key senior team to help answer those questions about what had been found.

Q Okay. Showing you 2291, based upon the results that came from this review process, were you later able to compare and see whether there was a significant difference between the self-identifieds and the best evidence claimants when it came to these different categories? And just explain 2291, if you would.

A Yes, on the left-hand side there is a pie chart that shows the percentages of nature of exposure categories that the self-identified claimants fell into. So we see 77 percent of the B, D, and E, 19 percent fell into the A/C category, and 4 percent into the other category. On the right-hand side we see a pie chart that reflected what I'm referring to as the best evidence. This means there was no self-identification.

We have to go to the attached materials and analyze the attached materials in order to assign a nature of exposure category, and we see here the very similar results. We had 90 -- 79 percent B, D, and E's versus 77. The A's and C's turned out to be pretty much identical, and the opposite two percent

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difference. So this gave us confidence that we had a pattern that was evolving and was repeated in the best evidence review.

Q Okay. Is 2291 an accurate summary of the data that exists on that subject?

A Yes, it is.

Q Turning to 2292, what did you find out after the -- let me just ask did you have the opportunity to look at the results of the review to gather further information about how these -- how these claimants based upon their attachments compared to the benchmarks that applied to your work?

A Yes, and this slide summarizes that work. We did the same kind of review for the lung cancer claimants and the -- for the laryngeal cancer claimants, and we find the results of those analyses all were below the benchmarks.

Q Okay. Well, let's be --

A They did not exceed the benchmarks.

Q Let's be clear about this. Were you able to -- this slide reflects a comparison between the results of your review, on the one hand, and the benchmarks, on the other. Were you able to make that comparison with respect to all people who make claims that you reviewed for lung cancer? That is is the comparison one that you were able to make for all the claimants that you looked at?

A Yes, we could -- well, I don't recall how many did not provide sufficient information.

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Q Okay, so this is where they had sufficient information to make --
A Well, we had sufficient information, yes.
Q Okay.
A We did the very same thing we did with the other reviews.
Q Okay, and you said all claims did not exceed benchmarks with respect to both lung cancer and laryngeal cancer?
A That's right. And you'll recall that those are very high benchmarks on Dr. Moolgavkar's benchmark chart.
Q What did you find out with respect to their status as smokers?
A Well, we found, of course, there's a confounder with smoking, and we found that all of the lung cancer claimants but one was a smoker, and about 90 percent of the claimants who claimed laryngeal cancer were smokers.
Q Could you tell us to what extent -- strike that. Two two nine two, does it accurately summarize the data that you gathered with respect to the comparison of claimants to benchmarks on lung cancer and laryngeal cancer?
A Yes.
Q And also their smoking status?
A Yes.
Q Okay. Turning to 2293, let's turn to mesothelioma and mesothelioma for people in Categories A and C, the ones that passed through the filter. Could you tell us in cases where it

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was possible to make the determination based upon the data that you had how the A -- the mesothelioma claimants who fell into Categories A and C, how they compared with the benchmarks?

A Yes, this was interesting, because for those claimants who gave us information about that duration of exposure, we were able to adjust the duration from 45 years to the number of years they gave us, and, of course, then we had to go back to that rolling average, those tables, and select for that time period that they gave us, what the exposures would be. But in essence what we find for the A's and C's is that 98 percent are lower than 15 fibers per mil year, and 16 percent are lower, and that's the benchmark that's at the bottom of the range of observation. And we found 69 percent are lower than the 8.9 fibers per mil year.

So that's just one adjustment from the very high screening values we used. All of the others are in here, the 100 percent exposure, frequency 250 days a year. The only adjustment is just the duration adjustment we could claim.

Q I want to make that very clear. You went back to the PIQs, and based on the review you looked to the people who had fallen into Categories A and C and had mesothelioma, and where the information regarding duration was available you substituted in your risk assessment calculation the actual duration as reflected in --

A Correct.

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Q -- the PIQ. But when it came to the other assumptions that you made, that is regarding the product that they were exposed to where you maximized the product concentration and the very -- and the other assumptions that you used, did you change those conservative assumptions to be in a sense actual based upon the PIQ data, or did you continue to make those other conservative assumptions?

MR. MULLADY: Your Honor, objection.

A Continued to make all of the other conservative --

MR. MULLADY: Objection, Your Honor. Excuse me. I've been pretty tolerant of the leading up to this point, but this is a very important area of the case. I think we just heard Mr. Bernick testify for about five minutes.

MR. BERNICK: Well, actually, if you want to have the record read back, the witness said exactly the same point. That is that she had kept the other matters constant, and I wanted to make sure that the details of that were evident to the Court.

Q Happy to have the question rephrased, so that she can explain exactly what it is that you meant when you said in response to my question that you altered the duration alone. Just explain to the Court what you meant.

A All right. The only thing that we could glean from the questionnaire data that could be useful to this analysis that would alter the analysis in any way was the duration

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information. So we altered the 45 years to match the actual years that the claimants provided for us. We continued to use all of the other conservative assumptions, and the only other thing we did is to match -- for those years they claimed, we have to go back to that rolling, instead of 45 year, that time period, select the highest value for the year -- for each year in the time period and do that analysis. All of the other maximum values were retained, nothing else is adjusted.

Q Okay. On the basis of this analysis what conclusion did you reach with respect to the A/C claimants?

A I concluded that on the -- I wrote this to -- on the right-hand side that there's a very high probability that many or most of the A's and C's that we are saying should be further evaluated actually are generously passed through the screen and passed on for further evaluation, because we see here just the impact of the alteration of one very conservative factor.

Q Let's -- go ahead. Let's turn to 2294. Does this slide now relate to the B, D, and E mesothelioma claimants?

A Yes, it does.

Q And could you tell us what it is that this slide reflects?

A All right. This slide is a similar analysis. This is for the B's, D's, and E's, and in those claimant questionnaires where they gave us their duration of exposure, we did the very same thing. We went back and took that duration of exposure, went to the data tables for the history of the products that

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were in trades of commerce during that block of identified years, again selected the highest value for each year in the identified block, did the rolling average, and kept the highest value for those claimants. And what -- we altered absolutely nothing else.

We kept all of the maximum values, and what you see here is a shifting of the numbers. One hundred percent or less than the background -- I mean less than the benchmark except background, and I made a very similar conclusion here but a opposite one, and that is a very low probability, and no scientific evidence whatsoever that any of these B's, D's, and E's would exceed the benchmarks.

Q Okay, and does 2294 accurately summarize the data that came from that comparison?

A Yes, it does.

Q Turning to 2295, did you also look to see -- you had -- you told us that you assumed that people spent their entire lives -- eight -- working lives eight hours a day working with Grace product. Based upon your review of the PIQs, what did you find about what the actual evidence showed?

A Well, in the PIQs I found that 94 percent of the claimants in Category A and C asserted other claims against other entities, and in 93 percent of the B's, D's, and E's asserted claims against other entities. So this tells me that the 45 years is certainly too much. If they were doing other

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occupations, they could not have had that much exposure most likely.

Q And what would that have done to your cumulative calculations by category if they actually had factored in this actual data?

A Well, if they left the workforce of exposure to Grace products and went into the workforce of exposure to other products, these numbers would be lowered in a commensurate way.

Q Were you able to make this comparison or derive these data with respect to all the claimants that you looked at? That's all the mesothelioma claimants.

A I can't recall, but I think most of them that we reviewed did provide -- we were able to make this comparison.

Q Okay. Let's go back to then our Board 2296.

THE COURT: Mr. Bernick --

MR. BERNICK: Yes.

THE COURT: -- you said 15 minutes 40 minutes ago. I think what we're going to do is take the recess if you're going to be much longer. How long are you going to be?

MR. BERNICK: Is it really that bad, Your Honor?

THE COURT: Yes, it is.

MR. BERNICK: Well, I apologize. I have this question. The last strip, and I've got three questions.

THE COURT: All right. We'll finish.

MR. BERNICK: I know if I didn't make a

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representation about how much longer it would take --
Q Are we now in a position to peel off the last magnet and show the balance of the assessments that you did as reflected now in 2296?
A Yes.
Q Okay, and what conclusion did you reach with respect to Categories A and C when it came -- comes to the evidence that came from the PIQ review?
A Yes, I alluded to earlier, we have suggested that there's some scientific evidence that those claims should be further reviewed. For the B's, D's, and E's, we found no such evidence.
Q Okay. Question 1, have you reached any conclusion as to whether the process that you followed in conducting your risk assessment analysis complies with accepted methods for assessing whether there's scientific support for the claims that have been made against Grace that you reviewed?
A Yes, this is certainly accepted scientific methodology.
Q Are you aware of any other accepted or any other accepted or reliable scientific method for determining whether claims -- asbestos claims or claims of exposure and causation from asbestos, whether they are supported by reliable science? Is there any other accepted or reliable method for reaching that assessment?
A I am under -- I'm unaware of any other method that would

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allow one to answer that essential question I posed in the beginning, and that is our -- the claimants exposure groups getting their disease from Grace product exposure. Without doing this assessment, I have no idea alternatively how any methodology can answer that question.

Q Okay. With respect to the claims that fall into Categories B, D, and E, do you have an opinion on whether there is reliable science supporting those claims of disease as being caused in whole or in part by exposure to Grace asbestos? Do you have an opinion?

THE COURT: We -- I'm sorry.

MR. MULLADY: Objection for --

THE COURT: We --

MR. MULLADY: Objection for the record, Your Honor.

THE COURT: Will you read the question for me again, please?

MR. BERNICK: Yes.

Q Do you have an opinion about whether there is reliable science to support the proposition that the claims falling into B, D, and E were caused in part or in whole by exposure to Grace asbestos? Do you have an opinion?

A Yes, I do.

Q And what is your opinion?

MR. MULLADY: Objection. For the record, Your Honor, the objection is to foundation. This witness is -- and this

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will be borne out on cross examination. But for the record, the opinion is incompetent and without foundation, because the witness has not worked with any actual exposure data from any actual Grace claimants in this case. She has not taken time waited average exposure samples, or I should say Dr. Lees did not take time waited average exposure samples from any actual Grace claimants. She's not been presented with that data.

She has been provided with instead the results of point-in-time studies and a very -- of a very small number of studies done by Dr. Lees of other workers in the vicinity of Grace products at different times who were not claimants in this case. Average or mean values were taken by Dr. Lees from those limited numbers of studies and provided to the witness. She has in turn then used that data to make judgments about the merits of actual claimants' cases on the basis of that evidence and not the evidence submitted by the claimants themselves insofar as their time waited average exposures and quantitative metrics are concerned.

I could make -- I could say a lot more about this issue, but I think that's the essence of the foundational objection to the offer of this opinion.

MR. BERNICK: Well, the foundational objection would be properly lodged, although I didn't hear it, under Rule 702 and 703 of the Federal Rules of Evidence. Now, I asked the witness a very simple question in order to address any

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remaining or any -- just to address the objection.
BY MR. BERNICK:
Q In all the work that you did in coming to the point where you were about to answer the question that I just asked you, I take it from your testimony that you relied upon Dr. Lees' work, Dr. Moolgavkar's work, and you relied upon the PIQ analysis. Is that right?
A That's correct.
Q Okay, and I just want you to tell me whether the work and the materials that you relied upon for purposes of offering an opinion on whether these claims are supported by reliable science, are those materials and is that -- are they the kind of information and evidence that people within the field of risk assessment find to be reliable for purposes of offering opinions of doing scientific work in that area?
A Absolutely.
Q Okay. Is there any respect in which you believe that the materials that you've relied upon don't satisfy that requirement? That is the requirement that they be the kind of materials that experts within your field find reliable for purposes of their expert work?
A I found that reliable. It's what I would expect, and I would not have used them otherwise.
Q Thank you. And based upon that foundation and based upon the work that you have done, could you tell us what your

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opinion is as to whether there is reliable science as to claims falling within A and C -- whether there is reliable science to say that those claims of injury were caused by Grace exposure either in part or in whole? Is there such reliable science?

MR. MULLADY: Objection.

A For A's and C's --

THE COURT: Just a minute. I believe that this would go to the weight not to the admissibility. Once again, I'm going to have to consider all of this when I get all of this testimony in and have an opportunity to look at the entire record, but I -- so for now I'm going to overrule it. I believe this will go to weight not admissibility.

MR. MULLADY: Your Honor, just one more statement for the record --

THE COURT: Yes.

MR. MULLADY: -- to clarify our position. The objection is not to under Rule 702 and 703 in the sense that the witness cannot rely on the opinions of these other experts. It is not -- that is not the basis for the objection. The basis for the objection is that the work of these other experts does not put this witness in a position to draw the conclusions that she is drawing. In effect, the underlying predicate for the opinion she's giving is incompetent to deliver the result that she wants to present before the Court.

THE COURT: Your --

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MR. BERNICK: There's no such things as --

THE COURT: Your objection, if I understand it, essentially is going to the medical condition of the particular claimants involved. If I understand what you're saying, you're attempting, I think, to get to whether or not each individual claimant has a condition that is founded on a Grace product?

MR. MULLADY: Not exactly, Your Honor.

THE COURT: No. Okay.

MR. MULLADY: This more goes to the issue of exposure.

THE COURT: All right.

MR. MULLADY: The exposure estimates that she's using are averages of exposure TWA fiber concentrations gathered by Dr. Lees from a limited sample of observations of people who work around -- who have worked around Grace products. It's our position that in order to express a competent opinion on causation in this case, whatever witnesses Grace would tender this opinion through, would have to testify that on the basis of actual quantitative data from actual claimants and a review of those claimants' actual exposure histories, there is or there is not scientific causation. We do not have that from this witness, and we certainly didn't hear it from Dr. Lees or Dr. Moolgavkar, and that's the basis for our objection.

MR. BERNICK: Yes, well, the interesting thing is, Your Honor, that this is an argument that -- this is an